



In the Public Eye

News and Features

US cancer institute funds trial of complementary therapy

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The US National Cancer Institute, through its office of Complementary and Alternative Medicine, is funding phase III clinical trials of a controversial treatment for advanced pancreatic cancer.

The treatment protocol, the Gonzalez regimen, involves a program of dietary modification, nutritional supplements, and "detoxification" through coffee enemas. Patients with stage II-IV pancreatic cancer are being enrolled.

The study was established in 1993, when Nicholas Gonzalez submitted selected unpublished results of his cancer therapy to the National Cancer Institute. The initial cohort treated with his regimen comprised 11 patients with diverse cancers.

Anecdotal evidence led Gonzalez to concentrate his efforts on pancreatic cancer, which he thought was more responsive to nutritional therapy than other types of cancer.

Preliminary data showed that patients with pancreatic cancer who were treated by the Gonzalez regimen survived an average of 17.5 months longer than those receiving conventional chemotherapy.

On the basis of the results of this preliminary study, 90 patients with pancreatic cancer refractory to surgery were randomized to 1 of 2 arms: 45 patients received intravenous chemotherapy with gemcitabine hydrochloride, a nucleoside inhibitor, for 30 minutes once a week for 7 weeks; the other 45 patients ingested up to 150 dietary supplements daily and took coffee enemas. The supplements included animal glandular extracts, vitamins, trace minerals, papaya, and magnesium citrate. Pancreatic enzymes were also administered.

Both the study and its sponsors are controversial. Detractors point out that, although Gonzalez is a physician, he has never gone beyond the medical degree in terms of residencies or board certification.

His protocol, moreover, is based on a theory promulgated by the Scottish anat-

mist John Beard in the early years of the last century and popularized by a dentist, William Kelley, in the 1980s. This theory holds that cancer is one disease emanating from ectopic germ cells, which are allowed to grow as a result of a deficiency of proteases.

According to this theory, supplemental treatment with pancreatic enzymes is required to digest the cancerous cells. Coffee enemas are given to "stimulate" the liver to detoxify the cancers and to reduce the incidence of the tumor lysis syndrome.

This theory flies in the face of the modern understanding of neoplasia, which sees cancer as multiple diseases with genetic and environmental bases.

Despite unproved theories, the alternative regimen has received attention and an aura of credibility. Pancreatic cancer is rarely curable, so any regimen that has shown a possibility of increasing survival is worth studying.

Moreover, the National Center for



Dietary supplements, including papaya, are part of the protocol in treating pancreatic cancer

Complementary and Alternative Medicine is mandated to fund alternative and complementary treatments and subject them to the

same rigorous review as conventional treatments. The phase III trial is being conducted through a \$1.4 million grant given to Co-

lumbia University's Rosenthal Center for Alternative Medicine in New York. It is expected to run for 5 years.
